

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

#### Protocol summary

##### Summary

Objective: The aim of this study is to evaluate a Theory-based educational intervention to change air pollution preventive behaviors among pregnant women in Tehran. Design: A controlled clinical trial Setting: Prenatal care services in Tehran. Participants and eligibility criteria: 104 women with singleton pregnancy, 18-35 years old, gestational age less than 36 weeks and pregnancy without any complication will be classified into intervention and control groups, randomly. Intervention: A Transtheoretical Model (TTM)-based educational program consisted of three components: one- session motivational interviewing, a pamphlet and daily Short Message Service (SMS). The intervention will be implemented for intervention group; after one-month, follow up the data will be gathered through standard questionnaires. Main outcome variables: Constructs of TTM; the stages of change, self-efficacy and perceived benefits and barriers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012091010804N1**

Registration date: **2012-10-25, 1391/08/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-10-25, 1391/08/04

##### Registrant information

##### Name

Marzieh Araban

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

تهران

##### Email address

m.araban@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tarbiat Modares University

##### Expected recruitment start date

2012-03-19, 1390/12/29

##### Expected recruitment end date

2012-11-27, 1391/09/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

##### Public title

Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Main inclusion criteria: singleton pregnancy; maternal age between 18-35 years old; gestational age less than 36 weeks; uncomplicated pregnancy Main exclusion criteria: complicated pregnancy (Preeclampsia; gestational hypertension; gestational diabetes; preterm labor; bleeding)

##### Age

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tarbiat Modares University

**Street address**

South east Gisha bridge, Tarbiat Modares University,  
number 1 building

**City**

Tehran

**Postal code**

1411713116

**Approval date**

2011-09-23, 1390/07/01

**Ethics committee reference number**

5271065

**Health conditions studied****1****Description of health condition studied**

behavioral intervention for pregnant women

**ICD-10 code**

O94-O99, O

**ICD-10 code description**

Other obstetric conditions, not elsewhere classified,  
Maternal care related to the fetus and amniotic cavity  
and possible delivery problems

**Primary outcomes****1****Description**

TTM constructs( including: perceived benefits and  
barriers, stage of change and self-efficacy)

**Timepoint**

1 month

**Method of measurement**

questionnaire

**Secondary outcomes****1****Description**

none

**Timepoint**

none

**Method of measurement**

none

**Intervention groups****1****Description**

The intervention consisted of three components: one-  
session motivational interviewing, a pamphlet and daily  
Short Message Service (SMS).

**Category**

Behavior

**2****Description**

Control group will receive routine prenatal care.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Najmiyeh hospital

**Full name of responsible person**

Marzieh Araban

**Street address**

Hafez- Jomhourri cross section, Tehran

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tarbiat Modares  
University

**Full name of responsible person**

Seddigheh sadat Tavafian

**Street address**

Number 1 building, Tarbiat Modares University, south east Gisha bridge, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tarbiat Modares University

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Seddigheh sadat Tavafian

**Position**

Ph.D, Associate proffesor

**Other areas of specialty/work**

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tavafian@modares.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Marzieh Araban

**Position**

Ph.D student in health education

**Other areas of specialty/work**

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araban62@gmail.com, m.araban@modares.ac.ir

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*